13 May 2016
EMA/CVMP/337144/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of May 2016 meeting

Chair: Anja Holm

Vice-chair: David Murphy

17 May 2016, 09:00 – 19 May 2016, 13:00 - Room 2A

Declaration of interests

In accordance with the Agency's revised policy and procedure on the handling of declarations of interests, participants in this meeting are asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting will take place in full respect of the restricted involvement of Scientific Committee members and, where relevant, experts attending the plenary meeting, as announced by the Scientific Committee Secretariat at the start of meeting.

Disclaimers

Some documents mentioned in the agenda/minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

i. Adoption of the Agenda

ii. CVMP delegates list of intended participation and identified conflicts of interests

iii. Declaration of contacts between members and companies with regard to points on the agenda

iv. Adoption of the minutes of the previous meeting

v. Confirmation of topics for rapporteur's meetings and breakout sessions

Scientific Advice Working Party (room 2A)	Tue 17 May 2016	16.00-20.00

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

1. ESTABLISHMENT OF MAXIMUM RESIDUES LIMITS

1.1 Opinions

• **Substance** EMEA/V/MRL/003200/EXTN/0003 *Extension to bovine tissues and milk*	***For adoption***: CVMP opinion including EPMAR, CVMP assessment report ***For information:*** Summary of opinion

1.2 Oral explanations and list of outstanding issues

- No items

1.3 List of questions

• **Substance** EMEA/V/MRL/004380/FULL/0001 *Chickens*	***For adoption***: CVMP scientific overview and list of questions

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

- No items

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **DRAXXIN** EMEA/V/C/000077/X/0029 *Extension to include a new target species* *Cattle, pigs*	Rapp: C. Ibrahim Co-rapp: C. Muñoz Madero ***For adoption***: CVMP opinion, CVMP assessment report ***For information***: Summary of opinion

2.2 Oral explanations and list of outstanding issues

• **Product** EMEA/V/C/002723/0000 *New antiparasitic product* *Bees*	***For decision***: Need for oral explanation ***For adoption***: Scientific overview and benefit-risk assessment and list of outstanding issues; comments on product information
• **Product** EMEA/V/C/004239/0000 *New vaccine* *Rabbits*	***For decision***: Need for oral explanation ***For adoption***: Scientific overview and benefit-risk assessment and list of outstanding issues; comments on product information

2.3 List of questions

• **Product** *New vaccine* *Pigs*	***For adoption**:* Scientific overview and list of questions, comments on draft product information

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

• **Product** V/C/0004296 *New antiparasitic product* *Bees*	***For decision**:* Consideration on conditions for supply; comments from CVMP members

- ***For endorsement*:** EPAR module scientific discussion for LETIFEND (EMEA/V/C/003865/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Veraflox** EMEA/V/C/000159/II/0008/G *Quality*	Rapp: C. Ibrahim ***For adoption***: CVMP opinion, CVMP assessment report

3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

• **CORTAVANCE and Easotic** EMEA/V/C/xxxxxx/WS/0925 *Quality*	Rapp: C. Friis ***For adoption**:* List of questions
• **BLUEVAC BTV8** EMEA/V/C/000156/II/0007 *Quality*	Rapp: E. Werner ***For adoption***: List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

- No items

4 REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- No items

4.2 Article 34 of Directive 2001/82/EC

- No items

4.3 Article 35 of Directive 2001/82/EC

• **Veterinary medicinal products containing altrenogest to be administered orally to pigs and horses** EMEA/V/A/095 *ERA*	Rapp: C. Ibrahim Co-rapp: S. Louet ***For adoption***: CVMP opinion, CVMP assessment report ***For discussion***: Rapporteur's presentation
• **Veterinary medicinal products containing a combination of lincomycin and spectinomycin to be administered orally to pigs and/or poultry** EMEA/V/A/110 *Indications, dosage and withdrawal periods*	Rapp: B. Urbain Co-rapp: K. Baptiste ***For adoption***: CVMP opinion, CVMP assessment report
• **Veterinary medicinal products containing methylprednisolone hydrogen succinate presented as solutions for injection for intramuscular use in cattle** EMEA/V/A/119 *Withdrawal periods*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For discussion and decision:*** Notification from Germany under Article 35 of Directive 2001/82/EC; appointment of rapporteur, co-rapporteur and peer reviewers ***For information***: List of products concerned

4.4 Article 78 of Directive 2001/82/EC

- No items

4.5 Article 13 of Regulation (EC) No 1234/2008

- No items

4.6 Article 30(3) of Regulation 726/2004

- No items

4.7 Other issues

- No items

5. POST-AUTHORISATION ISSUES FOR COMMUNITY MARKETING AUTHORISATIONS (EXCLUDING VARIATIONS)

5.1 General issues

- No items

5.2 Post-authorisation measures and annual reassessments

- No items

5.3 Product anniversary list

Product	Period
CERTIFECT (EMEA/V/C/002002)	06/05/2015 – 05/05/2016
Equilis StrepE (EMEA/V/C/000078)	07/05/2015 – 06/05/2016
Improvac (EMEA/V/C/000136)	11/05/2015 – 10/05/2016
Meloxidolor (EMEA/V/C/002590)	22/04/2015 – 21/04/2016
Naxcel (EMEA/V/C/000079)	19/05/2015 – 18/05/206
Oncept IL-2 (EMEA/V/C/002562)	03/05/2015 – 02/05/2016
Versican Plus DHPPi/L4 (EMEA/V/C/003678)	07/05/2015 – 06/05/2016
Versican Plus DHPPi/L4R (EMEA/V/C/002759)	07/05/2015 – 06/05/2016
Zuprevo (EMEA/V/C/002009)	06/05/2015 – 05/05/2016

5.4 Renewals

• **Recocam** EMEA/V/C/002247/R/0008	Rapp: D. Murphy Co-rapp: W. Schlumbohm ***For adoption***: CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

- ***For endorsement:*** Report to CVMP on 2015 Signal detection outcomes – 01.01.15-31.12.15, presentation of 2015 Signal detection outcomes to CVMP

• **Cerenia** EMEA/V/C/000106	Rapp: C. Friis ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.15-31.12.15
• **Contacera** EMEA/V/C/002612	Rapp: S. Louet ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.15-31.12.15
• **Nobilis OR inac** EMEA/V/C/000062	Rapp: H. Jukes ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.13-31.01.2016
• **Porcilis PCV ID** EMEA/V/C/003942	Rapp: P. Hekman ***For adoption***: CVMP assessment report on the PSUR for the period 28.08.15-29.02.16

• **Trifexis** EMEA/V/C/002635	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 05.07.15-04.01.16
• **Vectra 3D** EMEA/V/C/002555	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.15-31.12.15
• **Vectra Felis** EMEA/V/C/002746	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.15-31.12.15
• **Veraflox** EMEA/V/C/000159	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 01.11.14-31.10.15
• **Versican Plus Pi** EMEA/V/C/003681	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.15-31.01.16
• **Versican Plus Pi/L4R** EMEA/V/C/003682	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.15-31.01.16
• **ZULVAC 8 Bovis** EMEA/V/C/000145	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.15-31.01.16
• **ZULVAC 8 Ovis** EMEA/V/C/000147	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.15-31.01.16

- ***For endorsement***: List of products and calendar for signal detection analysis

5.6 Supervision and sanctions

Information relating to GMP and Pharmacovigilance inspections will not be published as it would be undermining the purpose of such inspections

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- ***For endorsement***: Draft EU comments on VICH discussion document on the definition of "Biologics"
- ***For endorsement***: Draft EU comments on draft VICH GL54 Studies to evaluate the safety of residues of veterinary drugs in human food: General approach to establish an acute reference dose (ARfD)
- ***For discussion***: Draft EU comments on the concept paper on the need to elaborate on the next steps in the global approach to demonstrate bioequivalence

- ***For discussion***: Draft EU comments on the concept paper for a general combination products guideline
- ***For discussion***: Draft EU comments on the draft annex to VICH GL3 Guideline on stability: Stability testing of new veterinary drug substances and medicinal products

6.2 Codex Alimentarius

- ***For endorsement:*** Draft comments on the future work of Codex Alimentarius on Antimicrobial Resistance - *see also point 8.3*

6.3 Other EU bodies and international organisations

- ***For information:*** Report by the CVMP representative from the joint EC/EFSA scientific workshop on bee health, held in Parma, Italy on 10 March 2016
- ***For information:*** Global Animal Health Conference and workshops on good regulatory practice of the registration of veterinary medicinal products in an Asian context, 14-17 November 2016, New Delhi, India - Conference leaflet and outline of workshops; executive summary of 2015 Global Animal Health Conference

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

7.1 Scientific Advice Working Party (SAWP-V)

Information relating to SAWP procedures cannot be released at the present time as it is deemed to be commercially confidential

7.2 Quality Working Party (QWP)

7.3 Safety Working Party (SWP-V)

7.4 Environmental Risk Assessment Working Party (ERAWP)

7.5 Efficacy Working Party (EWP-V)

7.6 Antimicrobials Working Party (AWP)

7.7 Immunologicals Working Party (IWP)

7.8 Pharmacovigilance Working Party (PhVWP-V)

7.9 Novel therapy groups and related issues

7.10 Joint CVMP/CHMP AHEG on the application of the 3Rs

7.11 Other working party and scientific group issues

8. OTHER SCIENTIFIC MATTERS

8.1 MRLs issues

Information on certain MRL related issues cannot be released at the present time as it is deemed to be confidential

- ***For adoption:*** Revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009

8.2 Environmental risk assessment

Information on certain Environmental risk assessment related issues cannot be released at the present time as it is deemed to be confidential

- No items

8.3 Antimicrobial resistance

- ***For endorsement:*** Updated opinion of the Expert Advisory Group on Antibiotic Resistance (AMEG) on the use of colistin products in animals within the European Union
- ***For endorsement:*** Draft comments on the future work of Codex Alimentarius on Antimicrobial Resistance - *see also point 6.2*
- ***For information:*** Feedback on the 2nd meeting of EFSA BIOCONTAM – BIOHAZ Working Group held on 18 March 2016 concerning the request for a scientific opinion on the risk for the development of antimicrobial resistance due to feeding of calves with milk
- ***For information:*** Publication of the EMA/ESVAC defined daily doses for animals (DDDvet) and defined course doses (DCDvet)
- ***For information:*** Verbal report on the meeting held on 28-29 April of the EFSA/EMA expert group on Reduction of Need for Antimicrobials in Food-producing Animals (RONAFA)

8.4 Pharmacovigilance

- No items

8.5 Other issues

Information on other critical issues related to centralised procedures cannot be released at the present time as it is deemed to contain commercially confidential information

- ***For decision:*** Speaker opportunity at Horizon 2020 project PARAGONE Vaccines for animal parasites - consortium meeting in Ghent on 29-30 August, 2016; draft agenda
- ***For information:*** Simulation exercise for incident management plan for medicines for veterinary use

9. AVAILABILITY OF MEDICINES AND MUMS CLASSIFICATION

Information relating to availability of medicines cannot be released at the present time as it is deemed to be commercially confidential

10. PROCEDURAL AND REGULATORY MATTERS

10.1 Eligibility and appointment of rapporteurs, co-rapporteurs and peer reviewers

Information relating to notification of intent for new MRL applications and notification of intent and eligibility requests for community marketing authorisations cannot be released at the present time as it is deemed to be commercially confidential

- ***For decision:*** Transfer of rapporteurships from A.-M. Brady

10.2 Regulatory matters

Information relating to certain regulatory issues cannot be released at the present time as it is deemed to be commercially confidential

- ***For adoption:*** Q&A on solvents in the centralised procedure

11. CO-ORDINATION GROUP FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

- ***For information***: Draft agenda of the meeting to be held on 19-20 May 2016, draft minutes of the meeting held on 21-22 April 2016*;* chair's presentation

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion***: Draft questions of survey on appointment of rapporteurs
- ***For information:*** Election of the Chair of CVMP (3-year term) at the June 2016 CVMP meeting; procedure for the election of the CVMP chair

13. LEGISLATION

- No items

14. ANY OTHER BUSINESS

- ***For comments***: Press release of the meeting

ANNEX

NEXT MEETINGS OF THE CVMP AND OF ITS WORKING PARTIES

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	3R's
May 2016	17-19	19	25-26		31		24-25	31	17	26-27	
Jun 2016	14-16			21-22	1	29-30		1-2	14		
Jul 2016	12-14						5/6		12		
Sep 2016	6-8		22-23						6	22-23	
Oct 2016	4-6			11-12					4		